REMARKS

Reconsideration and withdrawal of the rejections of the August 27, 2004 Office Action is respectfully requested in view of the remarks and amendments herewith. The Examiner is thanked for considering claims 7, 8, 50 and 51 to be allowable if written in independent form.

I. STATUS OF THE CLAIMS AND FORMAL MATTERS

Claims 1, 3, 4, 6-9 and 11-75 are now pending. Claims 4, 7, 8, 28, 29, 49, 50, 51, 66, 68, 74 and 75 have been amended, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

No new matter is added.

It is submitted that these claims are and were in full compliance with the requirements of 35 U.S.C §112. In addition, the amendment and remarks herein are not made for the purpose of patentability within the meaning of 35 U.S.C. §§101, 102, 103 or 112; but rather the amendments and remarks herein are made simply for clarification and to round out the scope of protection to which Applicants are entitled. Support for the amended claims is found throughout the specification and the original claims.

II. THE WRITTEN RESTRICTION REJECTIONS ARE OVERCOME

Claims 1-4, 6, 9, 11-18, 23, 24, 25-39, 46-49 and 52-75 were rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. Specifically, the Office Action alleged that a sufficient number of species of "small molecules" were not described in the specification to provide full descriptive support of the genus encompassing all such molecular adjuvants. Applicants respectfully traverse.

The Office Action states that the "small molecules" used in the present invention "is a broad term encompassing a plethora of organic and non-organic molecules and is note defined in the instant specification [in] such a manner as to apprise the artisan of the scope of small molecules encompassed by the claims or that Applicant had possession of a representative number of species of 'small molecules'." Office Action at 3. Applicants respectfully disagree.

The specification states at page 7, lines 1-8:

> The coupling system may comprise a two- or three-step chain of well-characterised paired small molecules, joined to the antibody and the HLA class I molecule so as to form a stable bridge

> between the two. Examples of paired small molecules which might be used in this connection include (but are not limited to) biotin and avidin/streptavidin (Moro, 1997 Cancer Res. 57, 1922-1928; Altman et al, Science 274, 1996, 94-96), and calmodulin and calmodulin binding peptides (Neri, 1996, J. Invest. Dematol. 107, 164-170).

It is respectfully submitted that this description provides sufficient guidance to allow one of skill in the art to select appropriate paired small molecules for use in the present invention. Specifically, one of skill in the art would recognize that paired small molecules for use in the present invention to bind to each other with a sufficient strength to create the bridge between the antibody and the HLA class I molecule.

Along with biotin and avidin/streptavidin and calmodulin and calmodulin binding peptides, the present invention may be used with small molecules such as barnase and barnstar. One of skill in the art would recognize that such a pair of small molecules would useful in the practice of the present invention because barnase is 110-amino acid protein with no disulfide bridges and barnstar has 89 amino acids and binds to barnase with high affinity (KD = 10-14M, tighter than antibody/antigen complexes). Furthermore, those of skill in the art would recognize that leucine zipper systems also meet the requirements of the present invention and could therefore be used as the "small molecules" in the practice of the present invention.

Should it be considered necessary, Applicants will gladly provide a declaration describing various small molecule pairings that may be used in the practice of the present invention. Accordingly, it is respectfully submitted that the specification provides ample description as to the characteristics of small molecules for use in the present invention, namely that the molecules must be of a sufficient size to form a bridge between the antibody and the HLA class I molecule, and that the molecules must bind to each other with high affinity. Consequently, reconsideration and withdrawal of the written description rejections are respectfully requested.

III. THE ENABLEMENT REJECTIONS ARE OVERCOME

Claims 40-45 were rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one of skill in the art to make and use the invention. Applicants respectfully traverse the rejection.

Specifically, the Office Action stated that monoclonal antibodies C46, 85A12, H17E2, HMFG1, W14, 1F5, and 225.28s are essential to the claimed invention and therefore must be obtainable by a repeatable method set forth in the specification or must otherwise be readily available to the public. Applicants respectfully submit that all of the monoclonal antibodies discussed in the specification, specifically C46, 85A12, H17E2, HMFG1, W14, 1F5, and 225.28s are commercial antibodies that are publicly available from one or more of Sorin Biomedica, Serotec Ltd., Cambridge Bioscience, Signet Laboratories, Abcam, Antisoma, or Bristol Meyers.

Under 37 C.F.R. §1.802, even if access to biological material is "necessary for the satisfaction of the statutory requirements for patentability under 35 U.S.C. 112", "[b]iological material need not deposited, *inter alia*, if it is known and readily available to the public." Accordingly, it is respectfully submitted that the commercial availability of the antibodies precludes the need for a deposit. Consequently, reconsideration and withdrawal of the rejection under 35 U.S.C. §112, first paragraph, is respectfully requested.

IV. THE INDEFINITENESS REJECTIONS ARE OVERCOME

Claims 4, 9, 28, 29, 40-45, 66, 68, 74 and 75 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. The rejection is respectfully traversed.

Claims 4 and 9 were considered indefinite due to the recitation that the linking peptide is directly attached to the MHC class I molecule that is contrary to the recitation of the base claims from which each of claims 4 and 9 depend. Claims 4 and 9 have been amended herein. Accordingly, it is believed that the rejection is now moot.

Claims 9 and 52 were rejected as being indefinite for reciting a recombinant protein comprising an MHC class I moiety and a moiety comprising the attaching means. The Office Action states no antecedent basis is present for the recitation because the "small molecules" referred to in the base claims cannot be encoded as part of a recombinant protein. Applicants respectfully traverse this statement, and submit that as "small molecules" are not limited as to their form, it is within the present invention that the "small molecules" may be small polypeptides that could be encoded as part of a recombinant protein. Accordingly, the rejection is moot.

Claims 28, 29, 45, 74 and 75 were considered indefinite because the base claims were drawn to a single pharmaceutical composition, and there accordingly was not proper antecedent basis for the recitation of "one or more" of the compositions. Applicants respectfully submit that the present invention contemplates more that one composition that can be made according to the invention. Accordingly, the present invention also contemplates the compilation of one or more of these compositions into a kit, wherein the kit can contain a number of containers each having therein a composition. The various containers within a kit can therefore contain the same composition, or they may comprise a number of different compositions. Accordingly, the claims are not indefinite, as they merely refer to the possibility of there being present more than one composition made by the present invention. However, in order to clarify this point, claims 28, 29, 74 and 75 have been amended to specify that a single type of composition is claimed in each base claim. Accordingly, the rejection is now moot.

Claims 66 and 68 were rejected because a multiple dependent claim cannot dependent on more than one base claims. The claims have been amended herein such that the rejection is now moot.

Claims 40-45 were also rejected as being indefinite for reciting the "laboratory names" of the monoclonal antibodies. As stated above, the monoclonal antibodies recited in claims 40-45 are available commercially under these names, and no deposit is necessary. Further, one of skill in the art would readily ascertain that monoclonal antibodies were being described in these claims, such that none of the alleged confusion will result from the inclusion of these names in the claims. Accordingly, the rejection is moot.

In view of the amendments and remarks herein, reconsideration and withdrawal of the rejections under 35 U.S.C. §112, second paragraph, is respectfully requested.

REQUEST FOR INTERVIEW

If any issue remains as an impediment to allowance, an interview, with supervisory review, e.g., with the Examiner, and the Examiner's SPE, is respectfully requested prior to issuance of any paper other than a Notice of Allowance. The Examiner is additionally respectfully requested to telephonically contact the undersigned to arrange a mutually convenient time and manner for the interview. The Examiner is also invited to telephonically contact the undersigned if there are any minor, formal issues that need resolving prior to issuance of a

Notice of Allowance, with a view towards resolving such minor, formal issues via telephonic interview.

CONCLUSION

In view of these amendments and remarks, the application is in condition for allowance. Early and favorable reconsideration of the application, reconsideration and withdrawal of the objections and rejections, and prompt issuance of a Notice of Allowance are earnestly solicited.

Respectfully submitted,

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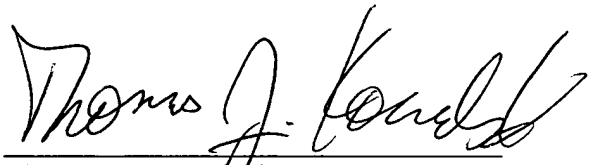
By: 

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